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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,364	01/12/2001	Jurgen M. Lehmann	018781000411	1585

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EXAMINER	
MURPHY, JOSEPH F	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/760,364	LEHMANN ET AL.	
	Examiner	Art Unit	
	Joseph F Murphy	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 33-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 33-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Formal Matters

Claims 1-9, 33-41 are pending and under consideration.

Response to Amendment

Applicant's amendment and arguments filed 9/29/2003 have been fully considered but they are not persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 -9 and 33-41 stand rejected under 35 U.S.C. 1 12, first paragraphs because the specification, while being enabling for methods of identifying agents that affect hypercholesterolemia does not reasonably provide enablement for identifying agents that affect CAR-related diseases that involve aberrant cholesterol levels, for reasons of record set forth in the Office Action of 6/25/2003. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The rejection of record set forth that Applicant's teachings indicate that disruption of CAR function results in hypercholesterolemia in mice. Thus, one of skill could predictably use effects on cholesterol as a means of identifying CAR effectors that would be useful for treating

hypercholesterolemia, and could predictably use CAR-deficient mice as models to identify agents that would be useful for treating hypercholesterolemia that results from CAR deficiency. Applicant has amended the claims to recite the limitation wherein the method identifies an agent for use in treating a CAR-mediated disorder that involves aberrant cholesterol levels. However, the term "aberrant cholesterol levels" is not clear as set forth in the rejection under 35 USC 112 second paragraph, *infra*. Thus the skilled artisan would not be apprised of the metes and bounds of this limitation with regard to cholesterol levels. While the specification discloses the role of CAR in hypercholesterolemia, it does not disclose that CAR activity can affect all possible aberrations of cholesterol levels. It would require undue experimentation for one of skill in the art to practice the methods as claimed, since the skilled artisan would have to first determine the role, if any, of CAR activity in the regulation of cholesterol levels other than hypercholesterolemia, then design assays for identifying agents which affect cholesterol levels other than hypercholesterolemia. Applicant is required to enable one of skill in the art to practice the claimed invention, while the claims encompass methods for which the skilled artisan would have to carry out further experimentation to determine the role of CAR in other types of cholesterol abnormalities, then design assays which would identify agents which could affect the resultant aberrant cholesterol levels, without clear direction form the specification of the role, if any, of CAR activity on the cholesterol levels, and additionally whether it would be possible for agents to affect these levels.

In addition claim 3 is directed to methods of identifying therapeutic compounds wherein the condition is listed as being lipid disorders or cardiovascular disorders. Applicant argues that hypercholesterolemia, lipid disorders, atherosclerosis or cardiovascular disease are conditions

that can inherently involve aberrant levels of cholesterol, and which can be predictably treated by therapeutic agents that lower elevated plasma cholesterol by modulating a CAR-mediated intermolecular interaction. However, the term "cardiovascular disorder" is a broad term and encompasses many different conditions, as shown in the Merck Manual, pages 1599-1601 (The Merck Manual of Diagnosis and Therapy, Beers and Berkow eds. Merck Research Laboratories, Whitehouse Station, N.J. 1999). This term encompasses several disorders that have no relation to cholesterol levels, such as arrhythmias (pages 1710-1717), endocarditis (pages 1763-1767) and cardiac tumors (pages 1774-1779). The etiology of arrhythmias is abnormalities of intrinsic automatic behavior or conduction (page 1711, column 2, third paragraph). The etiology of endocarditis is microbial infections of the endocardium, and cardiac tumors are tumors which may be epicardial, myocardial, or endocardial. The specification does not disclose the nexus between the function of CAR and its effect on cholesterol levels and any role of CAR in all cardiovascular disorders such as arrhythmias, endocarditis and cardiac tumors. It would require undue experimentation for one of skill in the art to practice methods of identifying therapeutic compounds wherein the condition is a lipid disorder or cardiovascular disorder, since the skilled artisan would need to determine the role of a CAR-mediated intermolecular interaction in cardiovascular disorders that are not caused by abnormal cholesterol levels, then design assays to identify compounds which could identify modulators of CAR-mediated intermolecular interaction which would affect these other disorders.

Claims 1 -9 and 33-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as originally filed does not provide support for the invention as now claimed: a method for identifying an agent for use in treating a CAR-mediated disorder that involves aberrant cholesterol levels.

Applicant's amendment of 9/29/2003, does not provide sufficient direction for the written description for the above mentioned limitations of claims 1 and 33. The specification as filed does not provide a written description or set forth the metes and bounds of this phrase. The specification does not provide direction for the limitation "aberrant cholesterol levels" as they are currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office action

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above.

Claim Rejections - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 -9 and 33-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 33 recite the term "aberrant cholesterol levels", which is a relative term and renders the claim indefinite. It is not clear to what standard the cholesterol levels are to be compared in order to determine whether they are "aberrant" or not. The metes and bounds of the claim thus cannot be ascertained. This rejection could be obviated by supplying specific parameters for cholesterol levels, supported by the specification, that Applicant considers to be "aberrant". Claims 2-9, 32-41 are rejected insofar as they depend on the recitation in claims 1 and 33 of "aberrant cholesterol levels".

Conclusion

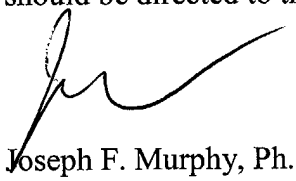
No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
December 10, 2003